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Integration of human factors and ergonomics during medical device design and development: It's all about communication

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ABSTRACT

Manufacturers of interactive medical devices, such as infusion pumps, need to ensure that devices minimise the risk of unintended harm during use. However, development teams face challenges in incorporating Human Factors. The aim of the research reported here was to better understand the constraints under which medical device design and development take place. We report the results of a qualitative study based on 19 semi-structured interviews with professionals involved in the design, development and deployment of interactive medical devices. A thematic analysis was conducted. Multiple barriers to designing for safety and usability were identified. In particular, we identified barriers to communication both between the development organisation and the intended users and between different teams within the development organisation. We propose the use of mediating representations. Artefacts such as personas and scenarios, known to provide integration across multiple perspectives, are an essential component of designing for safety and usability.

1. Introduction

Design can reduce the likelihood and consequences of error (Clarkson et al., 2004). Developing a system wide understanding of users, the tools that they use and the environments in which the live and work supports this approach (Carayon et al., 2006). For medical devices, such as infusion pumps, there are several examples of redesign that would reduce error rates (Lin et al., 1998; Thimbleby and Cairns, 2010). In these cases a valuable opportunity has been missed: once equipment has been deployed, it is difficult to update or modify it. There have been calls for an acceleration of the integration of Human Factors and ergonomics in patient safety, including the creation of "market forces for manufacturers to produce safer products that incorporate HFE [Human Factors Engineering] principles and techniques" (Gurses et al., 2012). HFE is a term applied to the application of theory, principles, data and methods to design in order to optimise human well-being and overall system performance. The European equivalent is Usability Engineering (UE), which is similar in principle. The aim of the work reported here is to better understand current practices in incorporating HFE into the design and development of interactive medical devices and, in particular, the challenges to doing so.

2. Background

In the European Union, the placing onto market of medical devices is governed by a number of European Council directives, implemented though national law. A medical device manufacturer is required to be: "reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used." They should provide: "consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users" (EC, 1993).

Modular, open, voluntary and harmonised standards support compliance with these requirements. One of these standards, IEC 62366 (2007) details the application of UE/HFE to medical devices. These interactions are broadly defined and include (but are not limited to) transport, storage, installation, operation, maintenance, repair and disposal. There is a need to consult a broad range of specialists during the design and development process. Knowing which stakeholders to contact and when is often a thorny issue (Sharp et al., 1999). For example, communication can be within an organisation, between an organisation and suppliers, or out to regulators, users or research providers. Coordinating exchanges is not easy and barriers to communication can arise due to a lack of common understanding. For example, in many industries, people use tacit knowledge that is difficult to express or share and rely upon shared cultural references that are only understood by people

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aware of the origins (Eckert et al., 2001, 2004; Eckert and Stacey, 2000; Eckert and Stacey, 2003; Flanagan et al., 2007). For medical devices, communication deficits have been shown to result in the wrong device being developed or purchased. For example, in a study examining requirements elicitation for a medical imaging device, when the intended clinical population was surveyed, they expressed little need for the device (Hinrichs et al., 2010; Martin et al., 2012).

Given the need for a broad range of specialists to work together, it can help to establish common ground. This is where mutual knowledge, beliefs and assumptions are identified (Clark et al., 1983). The concept of grounding can be likened to playing a duet on a piano, where players synchronise intros and exits, volume, tempo and dynamics. They also develop a mutual understanding of terminology, turn taking and limitations regarding the medium of communication.

Recent studies examining the relationship between healthcare professionals and equipment providers have found several barriers to the formation of common ground. Money et al. (2011) found that UE/HFE practice is constrained by an over reliance on limited numbers of senior healthcare staff. They also found an avoidance of consultation with patients or less senior staff, and a tendency to make design modifications on the basis of intuition rather than the more formal approach of user testing. There were biases towards collecting measures of efficacy to meet the needs of purchasing or evaluation agencies. The study also found a lack of clarity regarding who the user was and barriers relating to ethical process. For the later point, manufacturers raised concerns regarding the time it took to gain approvals. When involving patients, there were limitations in what could be achieved, when.

For relationships internal to the design and development process, recent reports regarding the application of IEC 62366 to the development of ventilator systems call for a better definition of roles and responsibilities (van der Peijl et al., 2012). The authors suggest that UE/HFE should be defined as a sub-process of the wider product development process and there should be greater linkages between UE/HFE and risk management. Associated research has flagged difficulties in translating user requirements to systems requirements, knowing when and where to invest development effort and managing the documentation burden (Fitch, 2004; Subita, 2007). There are accounts of difficulties in knowing when UE/HFE techniques should be applied, who is responsible for them, and integrating UE/HFE within existing development practice (Gupta, 2007; Mehrfard et al., 2010; Samaras and Horst, 2005). Many of these issues are addressed in textbooks or guides (NPSA, 2010; Weinger et al., 2011; Wiklund et al., 2010), suggesting that although knowledge is available, practitioners may have difficulty in accessing, locating or assimilating it.

We wanted to explore the challenges faced by those internal to the design and development process, when implementing UE/HFE. In a preceding qualitative analysis, reported elsewhere, we identified a range of challenges relating to the application of UE/HFE. Analysis was based on a smaller number of datasets (11). Issues included effective collaborative working practices; understanding the user and their situation; providing adequate justification for the adoption of a user-centred approach; the provision of clear guidance and support (Vincent and Blandford, 2011a); standardizing across the industry and understanding the regulatory intent (Vincent and Blandford, 2011b). In the preceding analysis, topics relating to communication and collaboration emerged repeatedly. We collected further data on that theme in order to conduct a focussed investigation, involving a greater number of participants and depth of analysis.

The questions we focused on were, what are the challenges to communication and collaboration during UE/HFE activities, and how can they be addressed? This could be in terms of making UE/HFE guidance more accessible, or supporting integration between disciplines. In order to understand how best to do this, we continued to conduct a qualitative study based upon interviews with those involved in the design, development and deployment of medical equipment (generally infusion devices) (Vincent and Blandford, 2011a, 2011b). It involved eight additional sets of data, collected using a theoretical sample. We examined ways in which device developers were incorporating technical, environmental and social aspects into the device design. We used thematic analysis to explore many of these issues, using the regulation, development, manufacture and deployment of infusion devices as foci. Although we did not set out to explore aspects regarding common ground, we found the concept useful in explaining the behaviours that were described.

3. Methods

3.1. Participants and data collection

We interviewed practitioners in order to build an understanding of current UE/HFE techniques and identify opportunities for support. Our definition of UE/HFE was not constrained by IEC 62366; rather, we allowed participants to define the terms as they wished. The topics for discussion are presented in Table 1.

We interviewed a range of professionals. The majority had an interest in the interactive properties of infusion devices (Table 2). Where possible, interviews were audio recorded and transcribed for analysis. When interviews were recorded, the audio recorder was clearly visible to participants, who agreed to be audio recorded.

In cases where it was not possible to take a recording, extensive notes were taken. Data were transcribed and loaded into ATLAS Ti (Scientific Software Development GmbH). The first author conducted the interviews and performed the analysis, in discussion with the other authors, as described in more detail below. We made the final paper available to participants to check that their views were accurately represented.

3.2. Levels of analysis, themes and meta-themes

The first author conducted a process of coding by defining chunks of data in a systematic fashion. Codes were abstracted to

Table 1
Interview topics.

Topic	Description
T1: Personal Background, Organisational Structure	Practitioner role and responsibility, internal and external relationships and dependencies.
T2: Fit in Landscape	Known stakeholders.
T3: Example Product	Example product including interactive properties.
T4: Awareness of Standards and Support	Awareness, interpretation, utility and relevance of design guidelines and standards.
T5: Interface Design Methods	Awareness, interpretation, utility and relevance of UE/HFE tools, details of development process.
T6: Interface Design Challenges	Mechanisms to prevent input error, interface design drivers/trade offs. Fit within development process.
T7: Interface Design Assessment	Application of user testing, evaluative techniques, verification and validation. Fit within development process.
T8: Post Marketing Activities	Training, user documentation, monitoring of device alerts and recalls, opportunities for support, constraints and dependencies.